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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,419	11/12/2003	Jingkun Li	19596-0551 (45738-294417)	7609
23370	7590	05/31/2005		EXAMINER
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/712,419	LI, JINGKUN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 8,11-19 and 21-25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7,9,10 and 20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_



**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 March 2005 has been entered.

2. Claims 1-25 are pending.

***Election/Restrictions***

3. Newly amended claims 8 and 10-13, and newly submitted claims 14-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- Newly amended claim 8 recites a method for isolating or concentrating a substance from a sample follows by analyzing said substance, classified in class 435, subclass 243, for example.
- Claims 1-7, 9, 10 and 20 are directed to a device and method for analyzing an analyte, classified in class 435, subclass 7.1, for example.

4. These inventions are distinct, each from the other because these two methods are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions,

or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The method for isolating and concentrating a substance recited in claim 8 comprises an analyzing step that is different from the analyzing step of claim 1.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8, 11-19 and 21-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 10 and 20 recite a generic device that may be used in either method, therefore, they have been included with the elected group and will be examined.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 9, 10 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Noda et al (US 5,900,379).

Noda discloses a test kit comprising a lateral flow device having a section that is removable. The removable section comprises a capture region where immobilized antibodies are used to capture an analyte. See column 5, lines 35-44; and column 11, example 1.

8. Claims 1-4, 7, 9, 10 and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by LaBorde (US 6,607,922).

LaBorde discloses an immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture analytes in a sample. The particles are disposed on a test strip that can be removed from a support member for archival or analysis by appropriate means. See column 2, lines 5-15; column 3, lines 13-30; and column 4, lines 13-17. LaBorde teaches that the removable test strip is stable and can be achieved either before or after being read. The analytes contained in the capture zone remain there, labeled with the conjugate combination. See column 5, lines 48-63. Even though LaBorde does not specifically teach a test kit comprising such a device; labored anticipates the instant kit claim because it is nothing more than the device itself with no additional components.

***Claim Rejections - 35 USC § 103***

**9.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**10.** Claims 1, 3-6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al (5,491,068) in view of Whitehead et al (US 4,695,393).

Benjamin discloses a method comprising contacting a sample with magnetic solid support beads having antibodies immobilized thereon. If present, the target selected bacteria cells binds to the antibodies and the beads with attached immobilized bacteria are then washed to remove any remaining sample. The beads with the immobilized bacterial are spread on a culture medium and the bacteria are allowed to grow to form colonies. To confirm that the colonies are the bacterial of interest, the colonies are contacted with a colony lift membrane, and the membrane can be subjected to several detection/analytical procedures by which the presence or characteristics of the bacteria are determined. See column 4, lines 6-63.

Benjamin differs from the instant invention in failing to teach the magnetic solid support beads are part of a device.

Whitehead, however, teaches magnetic beads that are deemed suitable by Benjamin. Whitehead teaches that the beads are reusable and the covalent attachment

of molecules to the beads is appropriate for use in affinity chromatography separation and cell sorting. See column 2, lines 15-18; and column 10, lines 17-26. Whitehead teaches that magnetic particles are placed in polypropylene tubes and after samples and labels have been added. The tubes are placed on a magnetic rack consisting of a test tube holder with a cylindrical button magnetic at the bottom of each tube. The magnetic particles with antibody and bound tracer were pulled to the bottom of the tubes allowing the unbound tracer to be removed. See column 21, lines 40-54. The test tube containing the magnetic particles taught by Whitehead is seen to be equivalent to the device of the instant claims.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device taught Whitehead in the method of Benjamin because clearly, the magnetic beads of Benjamin must necessarily be in a container or tube in order to function. Benjamin teaches the advantages of using magnetic particles to facilitate the capturing, isolating and enriching of microorganisms in order to accurately identify and study them, and a skilled artisan would have had a reasonable expectation of success in using the method taught by Benjamin.

*Response to Arguments*

11. Applicant's arguments with respect to the Mazar reference have been considered but are moot because this rejection has been withdrawn in view of the claims amendments.

**12.** Applicant's arguments filed 3/11/2005 have been fully considered but they are not persuasive.

Applicant argues that the amended claims overcome the Noda reference because Noda fails to teach the removal of the membrane immunoassay from the cassette. Specifically, Applicant argues that the claims required that the portion of the device containing the bound analyte and immobilized binding partner, i.e. detection zone, is separated or separable from the remainder of the device. And that the separated portion is analyzed to provide information regarding the analyte.

These arguments are not persuasive. Noda clearly teaches the removal of the result section, i.e. detection zone, from the cassette. See column 11, lines 61-63. This clearly meets the limitation that the detection zone is separable from the remainder of the device. Noda clearly teaches that the section that provides the results comprising immobilized binding partner to the analyte (see column 3, lines 33-36; and claim 1), therefore, the limitation that the removable section is the section containing the bound analyte and the immobilized binding partner is met.

Furthermore, claim 10 recites that the device comprises structural features that facilitate separation of the detection zone from the remainder of the device. Such a limitation is clearly taught by Noda at column 8, lines 10-15. Noda teaches that the membrane immunoassay (result section or detection zone) is glued to the cassette support means, therefore, this recitation is seen to be the same as a "structural features that facilitate separation of the detection zone from the remainder of the device".

The argument that Noda does not teach that the separated portion is analyzed to provided information regarding the analyte is not persuasive. This is not a limitation of claims 9 and 10.

Applicant argues that LaBorde does not teach the separation of the capture region from the remainder of the test strip as claimed because LaBorde teaches peeling the entire test strip from the housing.

This argument is not persuasive. The recitation of "the remainder of the device" leaves open the interpretation that the "remainder" is the backing support strip. In which case, LaBorde clearly teaches removing the test strip or portion containing the immobilized binding partner and the bound analyte from the remainder of the device. The claims are not limited to only the removal of the capture region and nothing else, including the sample region, the control region, the labeled region, the wicking region or any other regions which may be present. Nor are the claims limited to the removal of the capture region away from these other regions, if present. Therefore, the rejection is consistent with the interpretation of the claims.

Applicant argues that the LaBorde fails to teach a device comprising structural features that facilitate the separation of the capture region containing the bound analyte and the immobilized binding partner from the remainder of the device. Applicant argues that LaBorde suggest the removal of the entire test strip and not a portion thereof.

This argument is not persuasive. See the discussion of the interpretation of "the remainder of the device" above. Furthermore, LaBorde teaches a device comprising a removable backing (12) for facilitating the removal of the test strip from the support backing. Therefore, LaBorde clearly teaches a structural feature that facilitates the separation of the capture region.

The argument that LaBorde suggests the removal of the entire test strip and not a portion thereof is not persuasive. Claim 1 requires that *at least* part of the portion containing the bound analyte and immobilized binding partner be removed from the remainder of the device. This recitation is not limited to, nor is it the same with, the removal of *only* a portion of the test strip.

### ***Conclusion***

**13.** No claim is allowed.

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
5/23/05